

# **Veterinary Drugs and Vaccines Used in Jordan: Regulations, Activities, and Challenges**

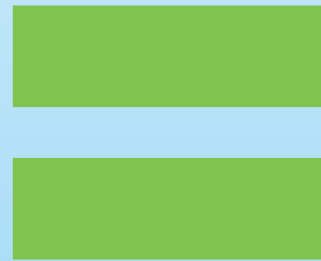


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**Ministry of Agriculture**

# Legal Provisions



Instructions No. (Z/4)  
for the year 2021




Manufacturing,  
Registration, Licensing  
and Circulation.

Article No. (44) of  
Agriculture Law No.  
13 year 2015.

# Definitions



New legislations, New terms  clarification ,controlling , and to avoid any confusing:

Medicine

Vaccine

Pesticide

Disinfectant

Pharmaceutical  
Industry

MLC

GMP

**Laws,  
Regulations,  
Guidances,  
Guidelines  
and  
Best Practices**



# Committee Members



# Committee of Registration Tasks

- Technical Committee is formed by the minister
- A - Registration of foreign manufacturers and licensing of local factories
- B- Inspection of local factories according to the rules of good manufacturing.
- C- Registering medicines, biological preparations and pesticides to permit circulation
- D- Renewing the registration every ten years
- E- Cancellation of the registration, modification or prohibition of the production or import



- F- Reconsider the registration of pharmaceutical companies, bio-products, or pesticides registered
- and to suspend or prevent the production, import or circulation of licensed products
- G- Decide a temporary or permanent ban on the production, import or circulation of any medicine,
- Biological preparation or veterinary pesticide and to cancel its registration by a reasoned decision.

# REGISTRATION



The general international practice for drugs, vaccines and pesticides is to be registered, before they can be introduced

It is helpful for good drug administration to be included in a National Formulary of Veterinary Drugs

Drug registration is according to ICH guidelines

Vaccine registration is done according to Emea or EP requirements and only the vaccine strains resemble the ones present in Jordan are registered.

All preparations must be passed from the lab before registration



3000 preparations,

Antibiotics , Coccidiosis -  
vitamins and minerals -  
hormones - de-worming and  
pesticides.

300 products which are  
Antibiotics in the form of  
Combinations

Colistin is studied now to be  
cancelled

Ciprofloxacin is studied to be  
cancelled

Some products as  
Azithromycin are refused to be  
used as a veterinary drug.

Ensure that the drugs are of  
good quality, safe, through  
inspection on plant for GMP

# ANTIBIOTICS USED

- POULTRY

Amoxicillin- Ampicillin- Gentamycin-Neomycin-  
Tetracycline -Chlortetracycline-Oxytetracycline -  
Doxycycline- Erythromycin-Tylosin- Tylvalosin-  
Tilmicosin- Lincomycin-Florfenicol-  
Thiamphenicol- Ciprofloxacin-Enrofloxacin-  
Norfloxacin- Flumequine-Colistin- Tiamulin-  
Trimethoprim with Sulphonamides

- LARGE ANIMALS

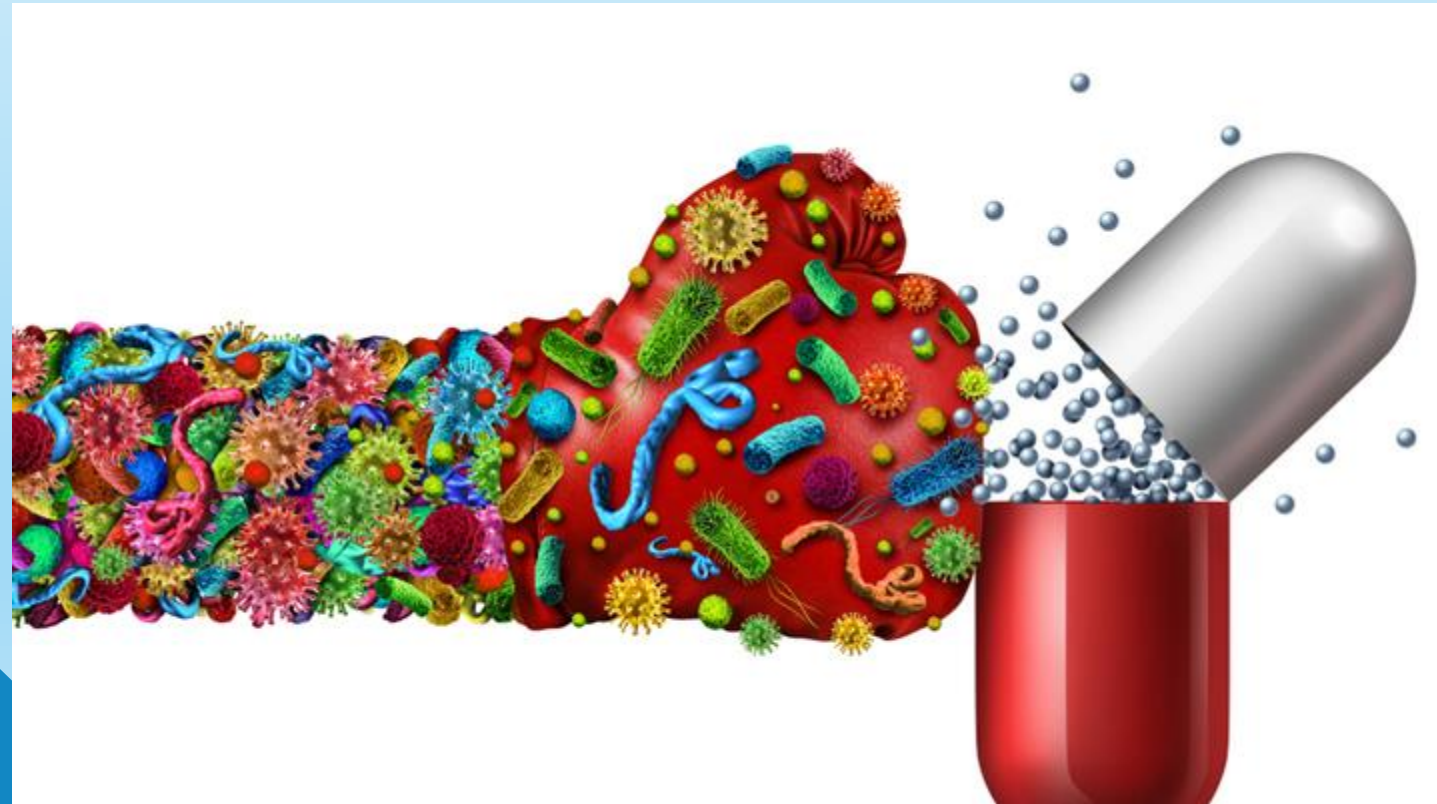
Oxytetracyclin – Ampicillin- Tylosin-  
Amoxicillin- Spectinomycin- Lincomycin-  
Streptomycin- Penicillin- Kanamycin-  
Enrofloxacin- Florfenicol- Marbofloxacin-  
Danofloxacin- Ceftiofur- Gentamicin-  
Tilmicosin- Colistin- Fosfomycin-  
Trimethoprim+Sulfa



# Pet Animals Drugs

Drugs used for pet animals undergo registration but in a less requirements, to decrease the use of pediatric drugs and in another way to decrease the entrance of counterfeit products.

# A special concern with Antimicrobials





Public Health  
England

# Antimicrobials: a simple overview

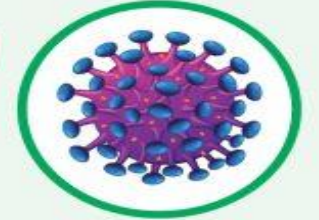
Prevent or treat  
infections caused by  
**Bacteria**



such as cellulitis, Urinary Tract  
Infection, tuberculosis (TB),  
Sexually Transmitted Infections  
(STIs) like gonorrhoea

**Antibiotics**  
(also known as  
antibacterials)

Prevent or treat  
infections caused by  
**Viruses**



such as colds, flu,  
chickenpox/shingles,  
COVID-19 or HIV

**Antivirals**

**Antimicrobials**  
are medicines  
used to prevent and treat  
infections caused by  
microorganisms in  
humans, animals and  
plants

Prevent or treat  
infections caused by  
**Fungi**



such as thrush, ring  
worm and athlete's foot

**Antifungals**

Prevent or treat  
infections caused by  
**Parasites**



such as malaria,  
threadworm and headlice

**Antiparasitics**

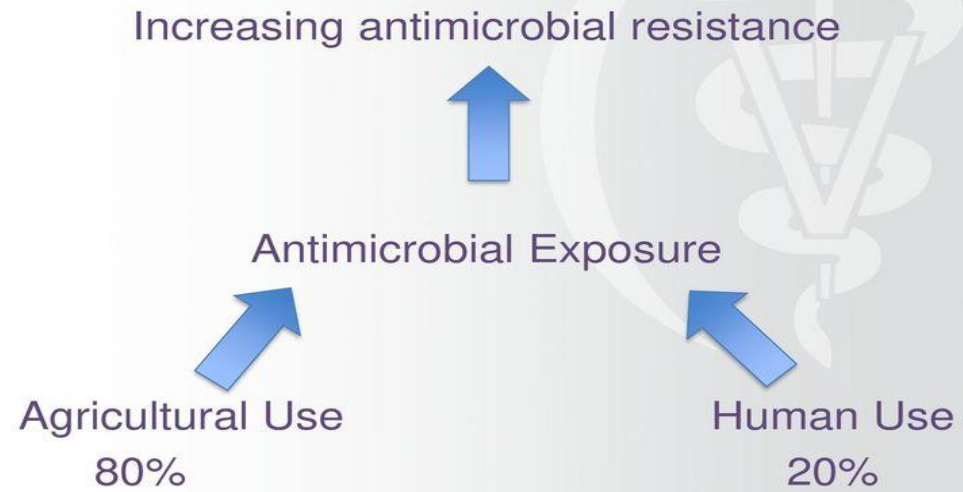
An antimicrobial  
drug works against **only one**  
type of organism

**Antimicrobial Resistance:**

when the microorganisms change or mutate over time  
and get to a point where they no longer respond to  
medicines previously used to treat them

# AMR

Why?



# Registration of Antibiotics

Antibiotics are undergoing with a strict registration procedures

Recent regulations prohibit the use of antibiotics as growth promoters

Regulations state that antibiotics must be sold only after registration and with a medical prescription , under the supervision of a veterinarian

Antimicrobial  
meeting  
international  
standards  
authorized

Antibiotics used  
as Growth  
promoter has  
been stopped.

Antibiotics show a  
cross resistance  
with human  
cancelled.

Antibiotics in  
premix is stopped.



**Rejection for  
registration of  
Antibiotics used in  
premix (Flavomycin)**

**Rejection for  
registration of  
antibiotics used in  
human (Azithromycin)**

The importation of raw  
materials is restricted to  
manufacturing plant.

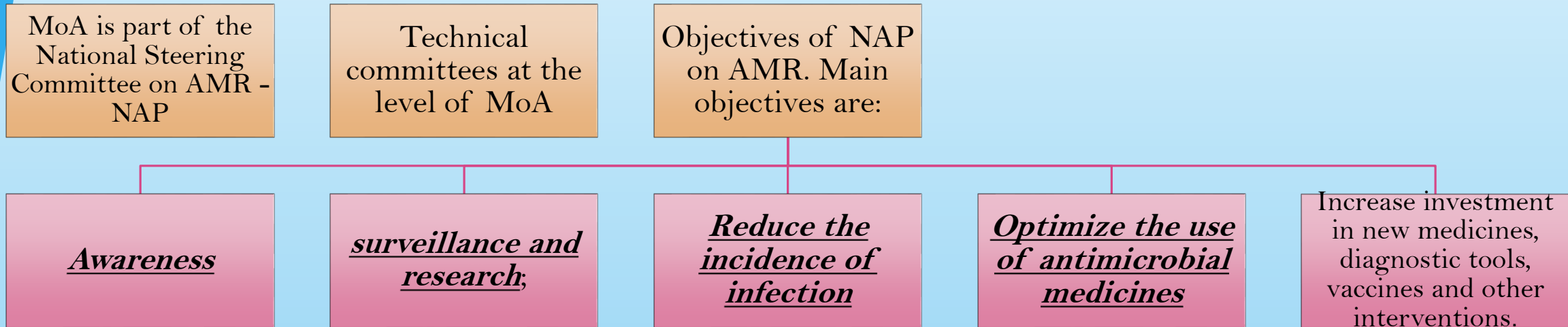
Add warning on  
the label to  
decrease the use  
of antibiotics

Add the  
withdrawal  
period on the  
label.

Poultry flocks  
accompanied by  
health certificate &  
pre slaughtering  
inspection report

Originator &  
Clinical studies

# Policies & Efforts Combating AMR



1- Addressing the abuse, overuse, and misuse of antimicrobials

2- Promoting good practices in AMU

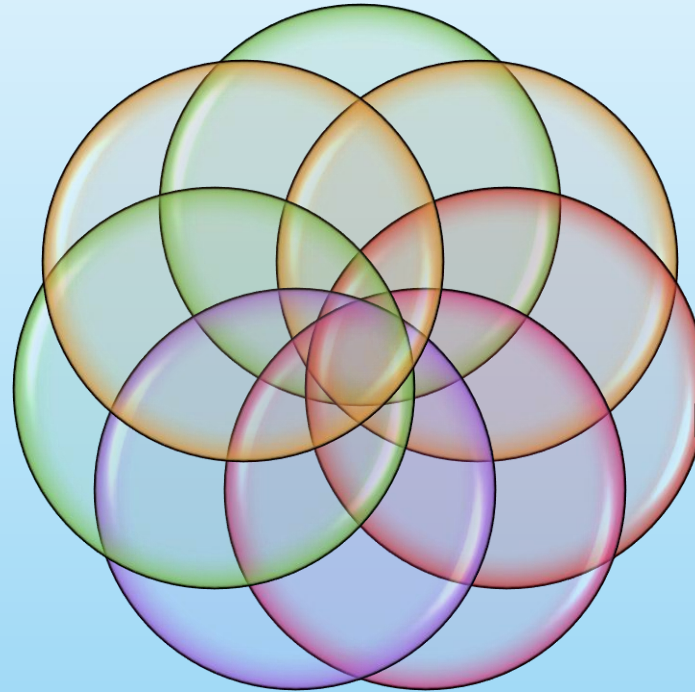
3- Implementation of good production and management practices.

4- Preserve antimicrobials as essential medicines for treating sick animals only

5- Prevent the introduction of counterfeit medicines

6- Control waste potentially contaminated with antimicrobials;

7- Control residues of antimicrobials in food, feed, water and soil



Establishment of acceptable daily intake (ADI), maximum residue limit (MRL) and withdrawal periods in food-producing animals

- methods for regulatory testing of residues in food are described based on the established marker residues.
- A list of withdrawal periods for each class of antibiotics is prepared and distributed to all farms through the associations (Veterinary, pharmacist and Engineers).
- formation of governmental laboratory to detect residues in Aqaba, and one under construction in the animal sector.
- Ask for certificates that detect residues of antibiotics for imported products

**Collection and reporting of AMU**

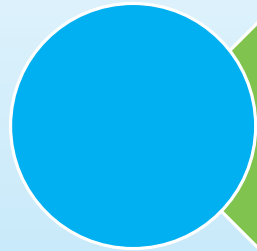
**2 . Development of a protocol to collect qualitative (e.g., types of antimicrobials on farm) and quantitative information on the antimicrobials intended for use in food producing animals**

**4. Information, where possible, on antimicrobial dose, dosing interval and duration.**

**1- Design of an integrated monitoring and surveillance program(s) for antimicrobial agents intended for use in food producing animals**

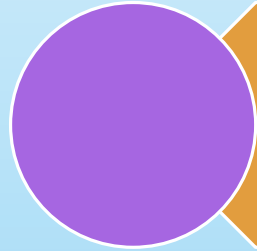
- the antimicrobial agents, classes or sub-classes).

**3. Identification of the level of detail required to meet the surveillance requirements (e.g., production type, route of administration or reason for use).**

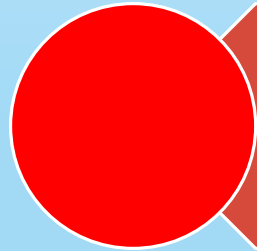


### Sources of sales/use data

- Sales data: collected from registration authorities

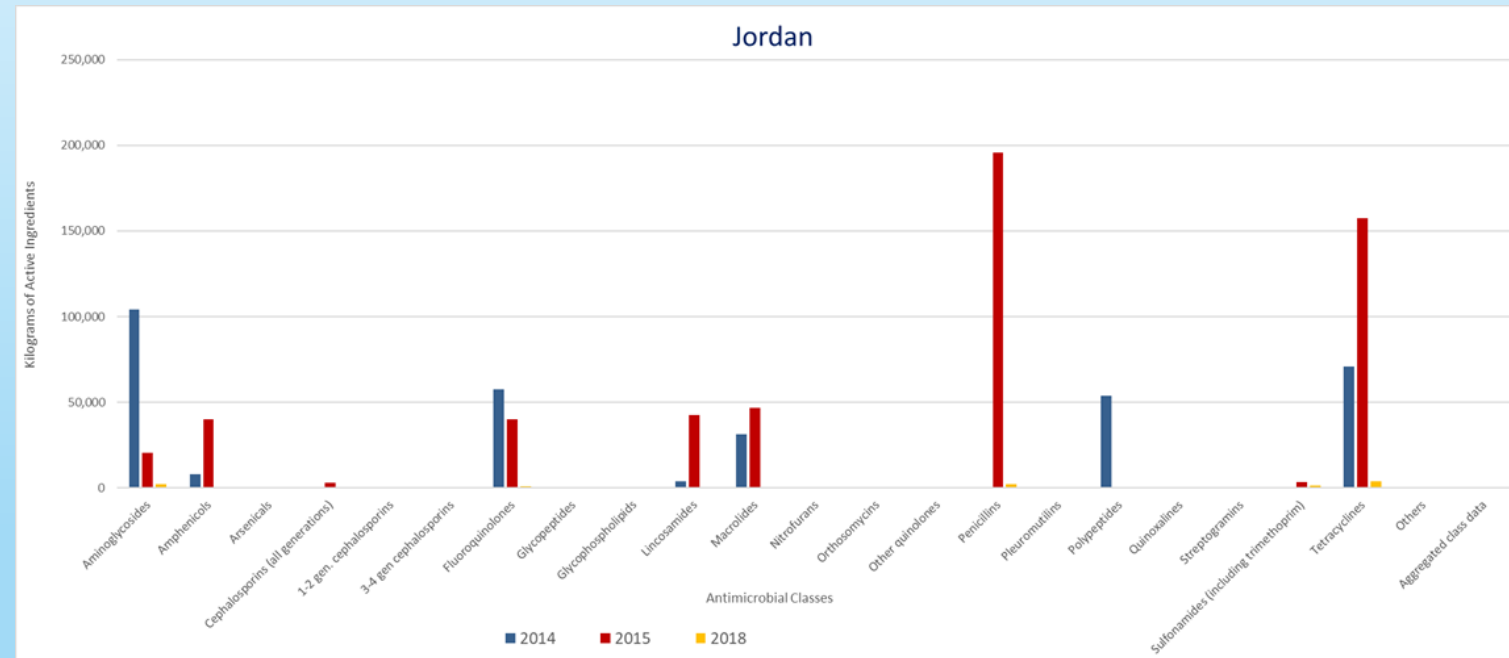


Import data: collected from the competent authorities that are in charge of registration of medicinal products or customs.



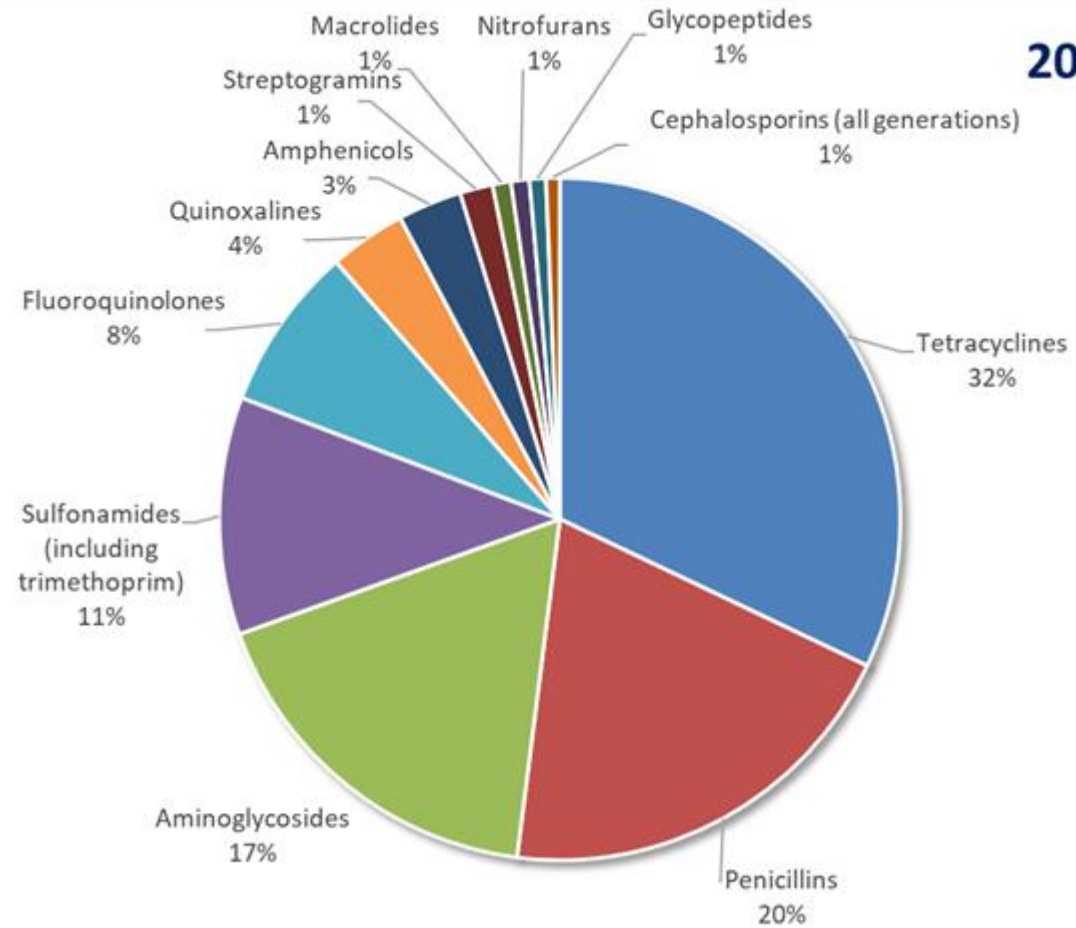
Analyzed of data for risk assessment , and add policies, and do Statistical analysis to ensure proper impetration of results

# Jordan consumption of Antibiotics





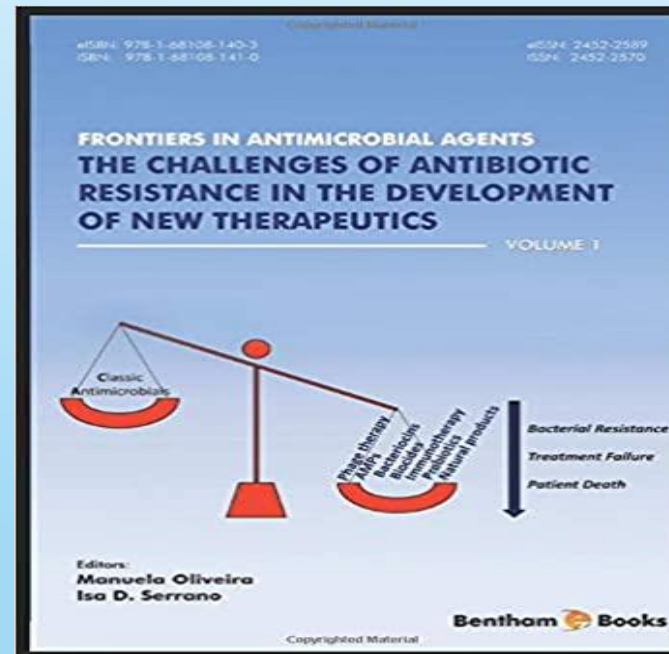
2018



## Protocol for the use of Antibiotics in Broiler Poultry flocks (0 - 35 days)

SELECT ONE OF THESE ANTIBIOTICS	VACCINES	SUSPECTED DISEASE	AGE							
Take all biosecurity measures, sterilize brix, and make sure of all tools	IB PRIMER + ND	—	0-1 DAY	Amoxicillin –	IBD	Intestinal problems, especially as a result of changing feed	12-15 DAYS	Doxycycline –	Respiratory infections	21 to 24 days (re-incubation) and usually depends on incubation at the beginning of the bird's life
				Amoxicillin with colistin –				THEN		
TYLOSIN ALONE – TYLOSIN WITH SULPHA AND TRIMETHOPRIM – TILMICOSIN – TILMICOSIN WITH SULPHA AND TRIMETHOPRIM – LINCOMYCIN –	ND + AI	Omphalitis	1-5 DAYS (The incubation period for the sauce CHICK	Gentamicin with Enrofloxacin - Ampicillin with colistin - Enrofloxacin with colistin and -amoxicillin –	ND ALONE			Tylosine –		
				Amoxicillin with enrofloxacin and colistin –	THEN					
				Ambrolium – Diclazuril – Toltrazuril –	IB					
					ND ALONE	COCCIDIA				
							19-20 DAYS	Doxycycline with Florphenicol – Erythromycin with Enrofloxacin – Erythromycin with Fosfomycin – Amoxycycline –	Respiratory and Intestinal infections	24 TO The age of sale depends on the problem and the nature of the problem that the bird suffers from

# CHALLENGES



1- The use of antimicrobials in healthy animals to prevent diseases

2- By eating animals and animal products (meat, milk, eggs, etc.), humans are liable to consume whatever chemicals the animal has consumed (withdrawal period)

3- Antimicrobials have been added -- in low dosages-- to animal feed to promote faster growth, as growth promoters

4- The cost of AMR to the economy is significant. In addition to death and disability, prolonged illness results in longer treatment, the need for more expensive medicines and financial challenges for those impacted.

# ACHIEVEMENTS



# ACHIVEMENTS



Governmental  
Laboratory to  
detect residues.



Calculate the  
exact quantities  
of antibiotics used



The quantities  
of the active  
raw materials  
imported are  
detected



Link  
professional  
registration  
requirements  
with website of  
ministry of  
Agriculture.



A list of  
withdrawal  
periods for each  
class of  
antibiotics is  
prepared

# RECOMMENDATIONS

Create a unit of pharmacovigilance

Development and upgrading of veterinary laboratories for the sensitivity of antimicrobials

**Increase awareness by vaccination of animals and use alternatives such as probiotics**



Recommendations

# RECOMMENDATIONS

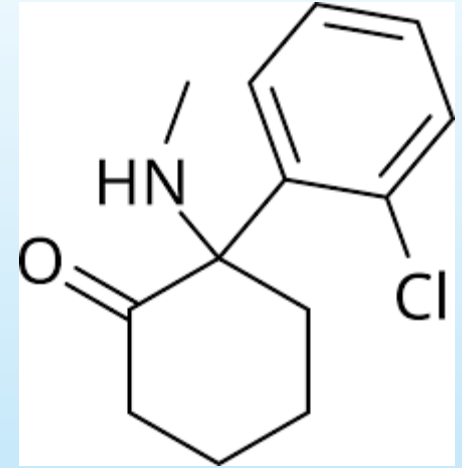
**Reviewed the registration of antibiotics in the form of combinations, and prepare a drug-drug interaction study beside safety and efficacy.**

**Application of biosecurity standards for the farms**

**Ensure the use of antibiotics under the supervision of veterinarian**



# KETAMINE



Consider as a narcotic drug



It is registered according to the routine requirement



Need special control for dispensing.

# GMP



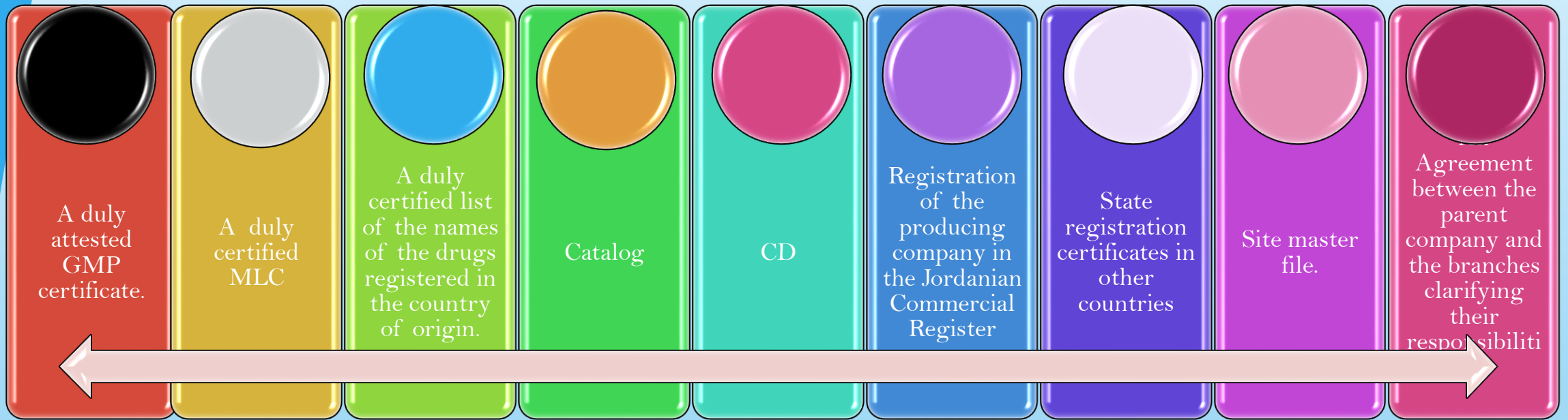
# COMPANY REGISTRATION

1- Must be a producer

2- Names of medicines or bio-products and pesticides manufactured by the company and registered in the country of origin

3- Date of incorporation of the company, the number of employees, their educational qualifications, and the business undertaken by the company

4- New innovations produced during the last ten years and the research and development budget



A duly attested GMP certificate.

A duly certified MLC

A duly certified list of the names of the drugs registered in the country of origin.

Catalog

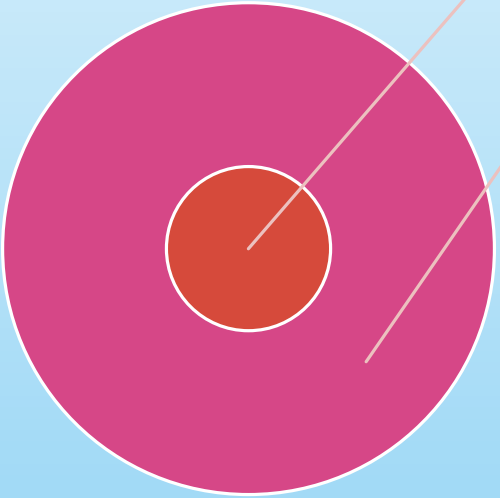
CD

Registration of the producing company in the Jordanian Commercial Register

State registration certificates in other countries

Site master file.

Agreement between the parent company and the branches clarifying their responsibilities



The guide is Eudralex

Inspection on local plant every 3 years and when required.



Control methods of drugs must undergoes these steps after manufacturing to ensure GMP

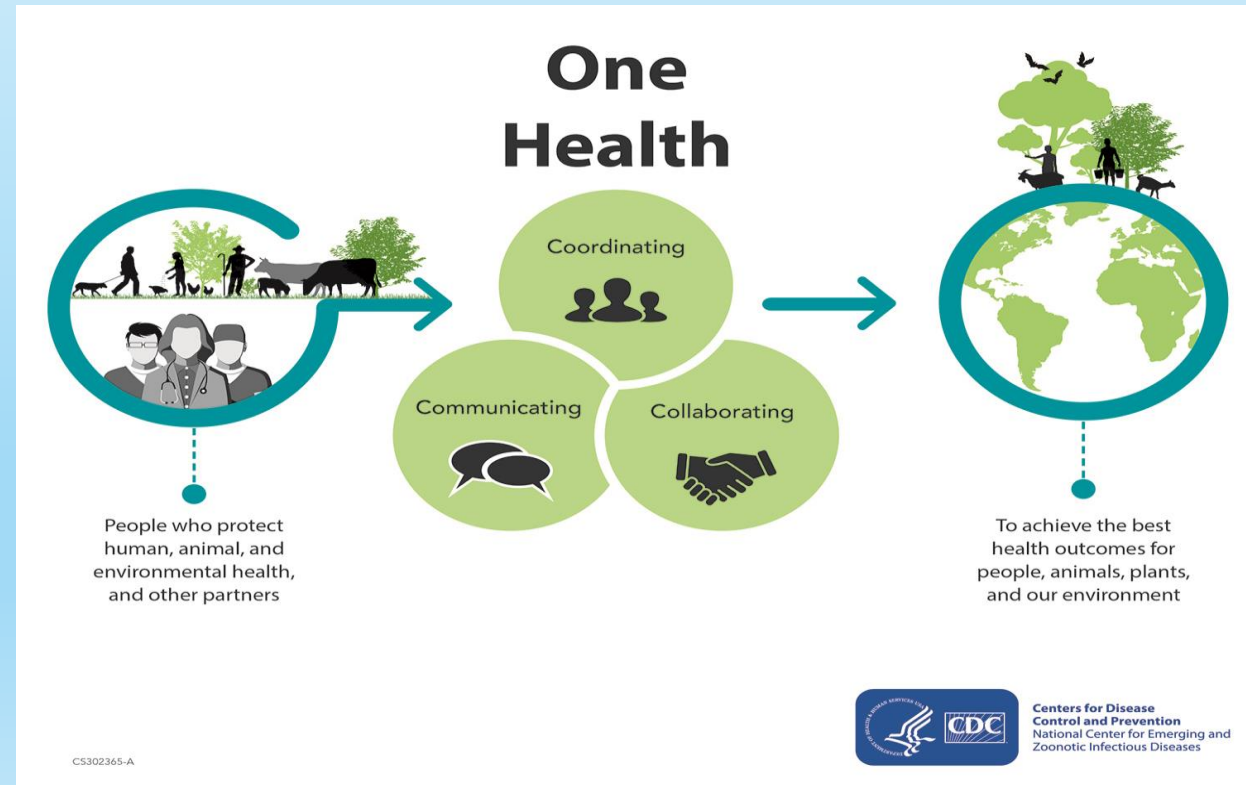
CONTROL



# THE GOALS OF VETERINARY DRUGS CONTROL

Protect public health

Preserve the health, production of the animals





**The  
committee  
has the right  
to cancel the  
registration :**

Re-registration is required every 10 years for validation.

its toxicity or ineffectiveness based on a report from the WHO, EU, or any scientific body approved by the committee.

its circulation has been prohibited or that it has been withdrawn in the country of origin

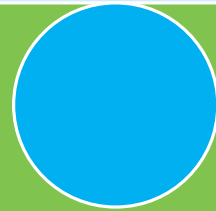
registered based on incorrect information



The  
registration of  
the company is  
canceled :

When the GMP  
Certificate is not  
provided upon  
request

# INSPECTION



The Ministry increased their inspection on pharmacies and veterinary stores and ask for the medical prescription of any antibiotic sold.

Also they sequestrate the illegal products (products which are un registered).

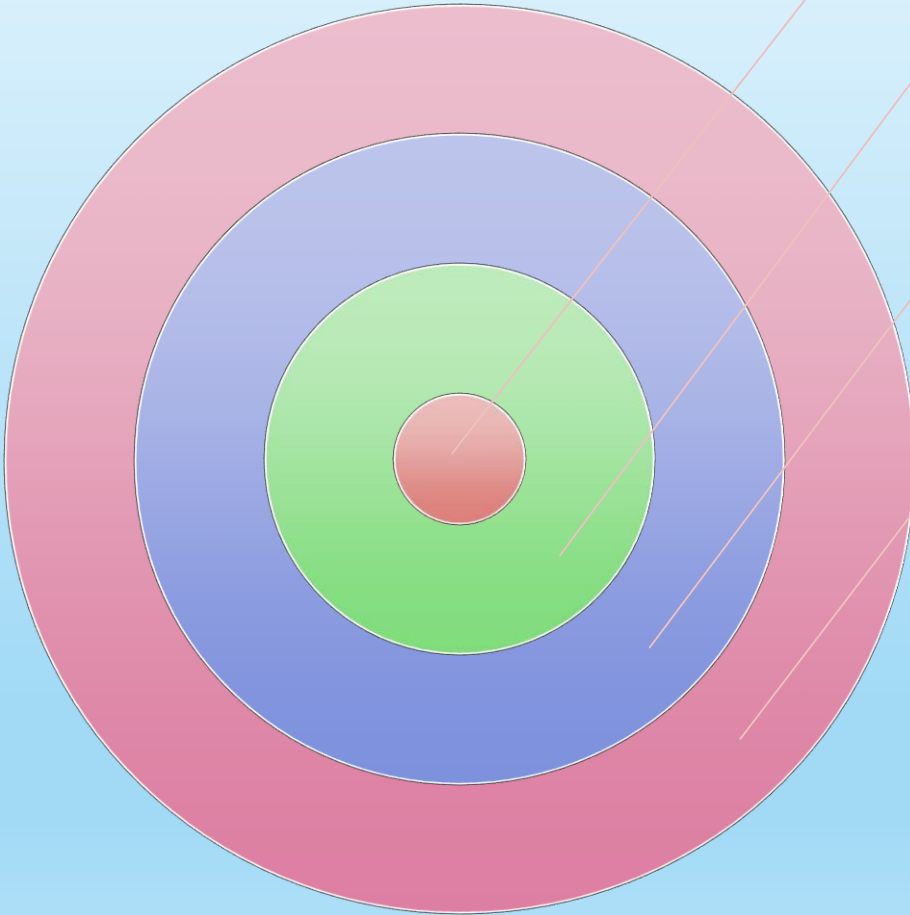



**Prohibited:**

Purchasing medicines, vaccines or pesticides except from the party licensed to sell them

Circulation of expired, damaged and worn out medicines, vaccines, pesticides or disinfectants

Disbursing medicine or feed additives that contain antibiotics except by a veterinarian





Customs and border posts employees not allowed to complete any data related

To the export of treatments, vaccines, disinfectants or veterinary pesticides except

After they are approved by the Pharmacy and Drug Control Department through an

Export permit (and/or) stamped invoice

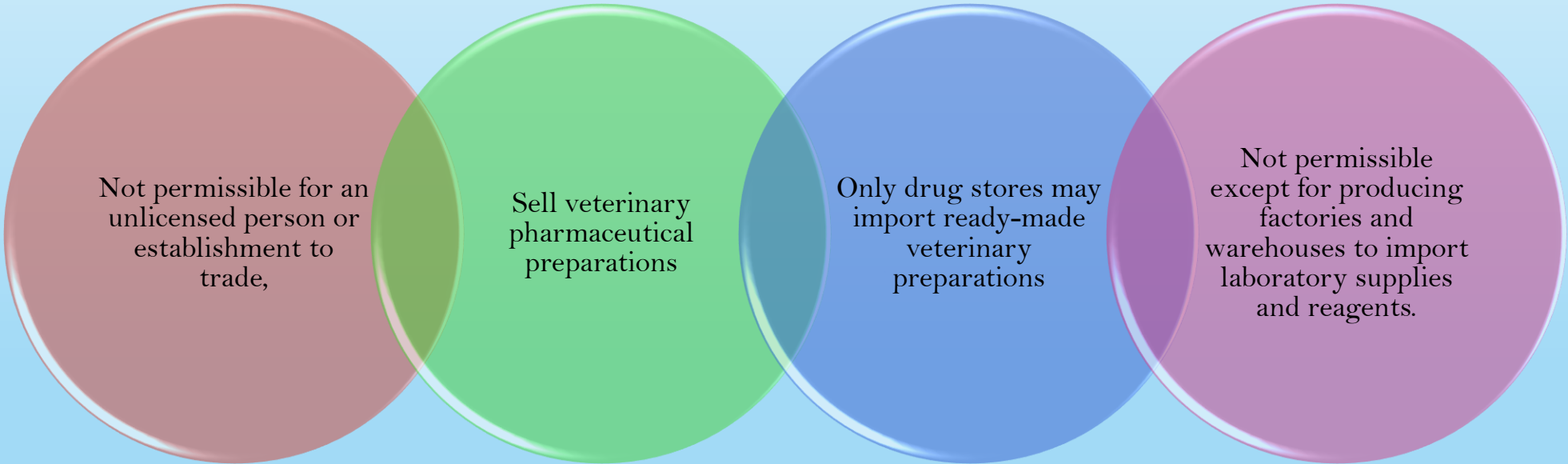

# IMPORTATION RULES

1- Manufacture, import, distribution or export whether wholesale or retail, with a license from the Ministry.

3- It is prohibited to circulate any except after its registration.

4- prohibited to import if the validity period is less than two-thirds of the period upon import

2- It is not permissible to import, except by the authorized agent who registered it and from the same country of origin.



Not permissible for an  
unlicensed person or  
establishment to  
trade,

Sell veterinary  
pharmaceutical  
preparations

Only drug stores may  
import ready-made  
veterinary  
preparations

Not permissible  
except for producing  
factories and  
warehouses to import  
laboratory supplies  
and reagents.



Importer must submit an invoice stating that the medicines comply with all conditions and specifications in the country of origin

In the case of importing from outside the producing countries, the importer must submit a certificate from the competent authority in the importing country, proving that the products are acceptable and sold there as they are accepted and sold in the producing country, and indicate the reasons for exporting from outside the country of production.



# DISINFECTANT



GMP for the manufacturer



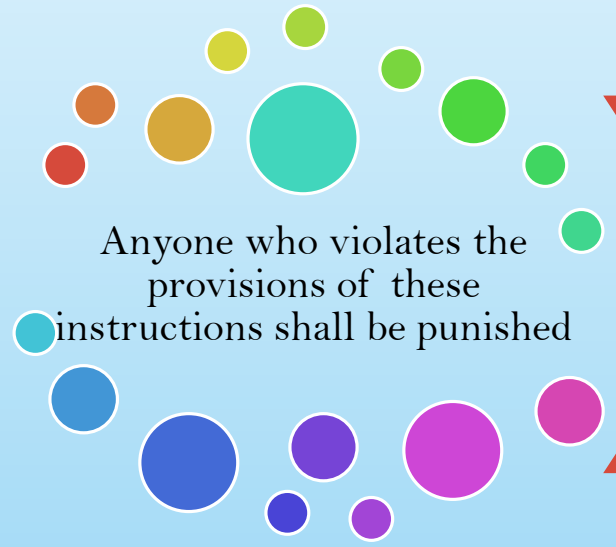
certificate of free sale



posters and leaflets showing the indications for veterinary use



MSDS



Anyone who violates the provisions of these instructions shall be punished



With the penalties stipulated in Article (44) of Agriculture Law No. 13 of 2015



